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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,128

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EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/762,128	Applicant(s) SCHOLLER ET AL.	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The preliminary amendment filed June 22, 2004 has been entered.

Claims 1-8 as originally filed are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 5, and 7, drawn to a vaccine comprising one or more recombinant expression constructs (i.e., DNA vaccine compositions), classified in class 514, subclass 44.
- II. Claims 2, 4, 6, and 8, drawn to a vaccine comprising the expression products of the recombinant expression constructs (i.e., protein vaccine compositions), classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the inventions are drawn to mutually exclusive and distinct compositions. The vaccine compositions are structurally, functionally, biologically, and chemically distinct. The vaccine of the invention of Group I comprises recombinant expression constructs, whereas the vaccine of the invention of Group II comprises protein. DNA vaccines function distinctly from protein vaccines and require the consideration of separate issues that are unique to vector vaccines. Furthermore, the specification does not disclose using the products of inventions I and II together. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions also have different designs, modes of operation, and effects. The vaccine compositions differ substantially in structure (i.e., they have different designs) as one comprises

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DNA expression constructs and the other comprises protein. The vaccine compositions also have different modes of operation because the DNA vaccine must first be taken up by cells residing at the injection site and then must be expressed by the cellular machinery before protein can be presented in combination with the appropriate MHC molecules. The protein vaccine functions distinctly in that it must enter the cell by a separate mechanism and must then be processed intracellularly. Thus, the vaccines have different modes of operation. The vaccine compositions also differ substantially in their effects because DNA vaccines allow prolonged expression of the antigen which is capable of generating significant immunological memory. Protein vaccines do not have this advantage and therefore the effects of the vaccine compositions are clearly distinct. Thus, the vaccine composition of the invention of Group I is patentably distinct from the vaccine composition of the invention of Group II.

Each of the inventions of Groups I and II requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the invention of Group I requires consideration of issues relating to enablement of a DNA vaccine for producing the desired effect, whereas consideration of issues specific to DNA vaccines is not required for examination of the invention of Group II. Likewise, the invention of Group II requires consideration of issues relating to enablement of a protein vaccine for producing the desired effect, whereas consideration of issues specific to protein vaccines is not required for examination of the invention of Group I. Furthermore, the searches for the inventions of Groups I and II are not coextensive. For example, a search for the DNA vaccine composition of the invention of Group I would not necessarily identify art teaching the protein vaccine of the invention of Group II, as protein vaccines and DNA vaccines are now often developed independently, particularly in the initial stages of development. Additional searching would be required to cover the method of the invention of Group II. Likewise, a search for the method of the invention of Group II would not be considered a comprehensive search for the DNA vaccine

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composition of the invention of Group I. Thus, search and examination of both inventions in a single patent application constitutes a serious burden on the Office.

With regard to burden, MPEP § 808.02 states that, to establish that there would be a serious burden on the examiner if restriction is not required,

“the examiner must show by appropriate explanation one of the following:

(A) **Separate classification thereof:** This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.” (emphasis original)

Thus, to establish that a serious burden exists, it is sufficient to show separate classification of the inventions. The instant inventions have separate classifications and require separate search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling

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please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.


ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER